We claim:

1. A method for transfecting a polynucleotide into cells, the method comprising:

combining:

(i) at least one polynucleotide;

(ii) a cationic lipid, a cationic polymer or a dendrimer, or a combination thereof; and

(iii) a solubilized cholesterol preparation

to form a transfection composition; and

applying the transfection composition to cells, such that the cells are transfected with the polynucleotide.

2. The method of claim 1, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

3. The method of claim 2, wherein the cyclodextrin is methyl-β-cyclodextrin.

4. The method of claim 2, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

5. The method of claim 1, wherein (ii) is a cationic lipid which is DOTAP.

6. The method of claim 1, wherein (ii) is a dendrimer which is Superfect.

7. The method of claim 1, wherein (ii) is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

8. The method of claim 1, wherein the polynucleotide is plasmid DNA.

9. The method of claim 1, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

10. The method of claim 1, wherein the cells are eukaryotic cells.

11. The method of claim 10, wherein the cells are mammalian cells.

12. The method of claim 11, wherein the cells are urothelial cells.

13. The method of claim 1, wherein the transfection composition is applied to cells in culture.

14. The method of claim 1, wherein the transfection composition is applied to cells *in vivo*.

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15. The method of claim 12, wherein the transfection composition is applied to urothelial cells *in vivo* by intravesical delivery to a bladder of a subject.

16. In a method for transfecting a polynucleotide into cells wherein the polynucleotide is complexed with a cationic lipid, a cationic polymer or a dendrimer and applied to cells, the improvement comprising formulating the polynucleotide and the cationic lipid, cationic polymer or dendrimer with a solubilized cholesterol preparation.

17. The method of claim 16, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

18. The method of claim 17, wherein the cyclodextrin is methyl-β-cyclodextrin.

19. The method of claim 17, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

20. The method of claim 16, wherein the cationic lipid is DOTAP.

21. The method of claim 16, wherein the dendrimer is Superfect.

22. The method of claim 16, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

23. The method of claim 16, wherein the polynucleotide is plasmid DNA.

24. The method of claim 16, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

25. The method of claim 16, wherein the cells are eukaryotic cells.

26. The method of claim 25, wherein the cells are mammalian cells.

27. The method of claim 26, wherein the cells are urothelial cells.

28. The method of claim 16, wherein the polynucleotide is applied to cells in culture.

29. The method of claim 16, wherein the polynucleotide is applied to cells *in vivo*.

30. The method of claim 27, wherein the polynucleotide is applied to urothelial cells *in vivo* by intravesical delivery to a bladder of a subject.

31. A method for delivering a pharmaceutical agent into urothelial cells of a subject, the method comprising:

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combining the pharmaceutical agent with a solubilized cholesterol preparation to form a pharmaceutical composition; and

delivering the pharmaceutical composition intravesicularly into the bladder of the subject, such that the pharmaceutical agent is delivered into

5   urothelial cells of the subject.

32. The method of claim 31, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

10   33. The method of claim 32, wherein the cyclodextrin is methyl-β-cyclodextrin.

34. The method of claim 32, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-

15   cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin,

20   carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

35. The method of claim 31, wherein the pharmaceutical agent

25   comprises: (i) at least one polynucleotide and (ii) a cationic lipid, a cationic polymer or a dendrimer, or combinations thereof.

36. The method of claim 35, wherein (ii) is a cationic lipid which is DOTAP.

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37. The method of claim 35, wherein (ii) is a dendrimer which is Superfect.

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38. The method of claim 35, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

39. The method of claim 35, wherein the polynucleotide is plasmid DNA.

40. The method of claim 35, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.

41. A method for treating bladder cancer in a subject, the method comprising:

combining a pharmaceutical agent with a solubilized cholesterol preparation to form a therapeutic composition, wherein the pharmaceutical agent has anti-cancer activity against bladder cancer cells; and

delivering the therapeutic composition intravesicularly into the bladder of a subject, such that bladder cancer cells of the subject are treated with the pharmaceutical agent.

42. The method of claim 41, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

43. The method of claim 42, wherein the cyclodextrin is methyl-β-cyclodextrin.

44. The method of claim 42, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

45. The method of claim 41, wherein the pharmaceutical agent comprises: (i) at least one polynucleotide and (ii) a cationic lipid, a cationic polymer or a dendrimer, or combinations thereof.

46. The method of claim 45, wherein (ii) is a cationic lipid which is DOTAP.

47. The method of claim 45, wherein (ii) is dendrimer which is Superfect.

48. The method of claim 45, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

49. The method of claim 45, wherein the polynucleotide comprises at least one expression vector encoding at least one protein selected from the group consisting of interleukins, interferons, colony stimulating factors,

anti-angiogenic factors, anti-metastatic factors, membrane receptors and tumor suppressors.

50. The method of claim 45, wherein the polynucleotide comprises an expression vector encoding a protein selected from the group consisting of interleukin-1 (IL-1), interleukin-2 (IL-2), interleukin-6 (IL-6), interleukin-9 (IL-9), interleukin-11 (IL-11), interleukin-12 (IL-12), interleukin-13 (IL-13), interleukin-18 (IL-18), interferon-α, interferon-β, interferon-γ, granulocyte-macrophage colony stimulating factor (GMCSF), granulocyte colony stimulating factor (GCSF), macrophage colony stimulating factor (MCSF), heat shock protein (HSP), p53, an antagonist of vascular endothelial cell growth factor (VEGF), a tissue inhibitor of metalloproteinases (TIMP), and a fibronectin receptor.

51. The method of claim 45, wherein the polynucleotide comprises an expression vector encoding interleukin-2 (IL-2).

52. The method of claim 45, wherein the polynucleotide comprises an expression vector encoding granulocyte macrophage colony stimulating factor (GMCSF).

53. The method of claim 45, wherein the polynucleotide comprises an expression vector encoding interferon-γ.

54. The method of claim 45, wherein the polynucleotide comprises at least one expression vector encoding two or more of interleukin-2 (IL-2), granulocyte macrophage colony stimulating factor (GMCSF) and interferon-γ.

55. The method of claim 41, which further comprises performing an additional anti-bladder cancer treatment on the subject.

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56. The method of claim 55, wherein the additional anti-bladder cancer treatment comprises Bacillus Calmette-Guerin (BCG) therapy.

57. A transfection composition comprising:

(i) a polynucleotide;

(ii) a cationic lipid, a cationic polymer or a dendrimer, or combinations thereof; and

(iii) a solubilized cholesterol preparation.

58. The transfection composition of claim 57, wherein the solubilized cholesterol preparation comprises cholesterol solubilized with a cyclodextrin.

59. The transfection composition of claim 58, wherein the cyclodextrin is methyl-β-cyclodextrin.

60. The transfection composition of claim 58, wherein the cyclodextrin is selected from the group consisting of alpha-cyclodextrin, beta-cyclodextrin, gamma-cyclodextrin, sulfated beta-cyclodextrin, tertiary amine beta-cyclodextrin, quaternary amine beta-cyclodextrin, 2-hydroxypropyl-beta-cyclodextrin, 2,6-di-O-methyl-beta-cyclodextrin, hydroxyethyl-beta-cyclodextrin, 6-deoxy-6-S-beta-D-galactopyranosyl-6-thio-cyclomalto-heptaose, sulfobutylether-beta-cyclodextrin, carboxymethyl-beta-cyclodextrin, carboxymethyl-ethyl-beta-cyclodextrin, diethyl-beta-cyclodextrin, dimethyl-beta-cyclodextrin, random methyl-beta-cyclodextrin, glucosyl-beta-cyclodextrin and maltosyl-beta-cyclodextrin.

61. The transfection composition of claim 57, wherein (ii) is a cationic lipid which is DOTAP.

62. The transfection composition of claim 57, wherein (ii) is a dendrimer which is Superfect.

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63. The transfection composition of claim 57, wherein the cationic lipid, cationic polymer or dendrimer is selected from the group consisting of DOPE, DOTMA, DOGS, DODAB, DODAC, DOSPA, DC-Chol, DOIC, DOPC, DMRIE, PAMAM, polylysine, polyhistidine, polyarginine, polyethyleneimine, poly(4-vinylpyridine), poly(vinylamine), poly(4-vinyl-N-alkyl pyridinium halide), or combinations thereof.

64. The transfection composition of claim 57, wherein the polynucleotide is plasmid DNA.

65. The transfection composition of claim 57, wherein the polynucleotide is selected from the group consisting of viral DNA, chromosomal fragments, antisense oligonucleotides, antisense phosphorothioate oligonucleotides, RNA molecules and ribozymes, or combinations thereof.